ATTY. DOCKET NO. APPLICATION NO. 18528.127 09/889,330 INFORMATION DISCLOSURE APPLICANTS STATEMENT BY APPLICAN Andrew A. YOUNG et al. 371 FILING DATE ART UNIT December 27, 2001 1614 U.S. PATENT DOCUMENTS EXAMINER INITIAL DOCUMENT PUBLICATION DATE CLASS FILING DATE AA1 6,506,724 B1 1/2003 Hiles et al. US 2003/ AB1 5/2003 Beeley et al. 0087821 A1 FOREIGN PATENT DOCUMENTS EXAMINER INITIAL DOCUMENT DATE COUNTRY SUB-CLASS CLASS TRANSLATION Yes No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) AMYLIN PHARMACEUTICALS, INC., Form 10-K "Annual Report Pursuant to Section 13 or 15(d) of the AC1 Siul Securities Exchange Act of 1934, March 15, 2002, pages 1-8. Baggio et al., "Sustained Expression of Exendin-4 Does Not Perturb Glucose Homeostasis, β-Cell Mass, or Food AD1 Intake in Metallothionein-Preproexendin Transgenic Mice," J. Biol. Chem. 275(44):34471-7 (2000). Edwards et al., "Exendin-4 Reduces Fasting and Postprandial Glucose and Decreases Energy Intake in Healthy AF1 Volunteers," Am. J. Physiol. Endocrinol. Metab. 281:E155-61 (2001). Egan et al., "The Insulinotropic Effect of Acute Exendin-4 Administered to Humans: Comparison of Nondiabetic AG1 State to Type 2 Diabetes," J. Clin. Endocrinol. & Metab. 87(3):1282-90 (2002). Goke et al., "Exendin-4 Is a High Potency Agonist and Truncated Exendin-(9-39)-amide an Antagonist at the Glucagon-like Peptide 1-(7-36)-amide Receptor of Insulin-secreting β-Cells," J. Biol. Chem. 268(26):19650-55 AH1 (1993) (previously submitted on August 20, 2002). International Search Report, International Application No. PCT/US03/16699 (August 2003) AI1

EXAMINER

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Tourrel et al., "Persistent Improvement of Type 2 Diabetes in the Goto-Kakizaki Rat Model by Expansion of the β-

Cell Mass During the Prediabetic Period with Glucagon-Like Peptide-1 or Exendin-4," Diabetes 51:1443-52 (2002).

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INFORMATION DISCLOSURE

| Application Number | Loo/200 230

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

of

(use as many sheets as necessary)

	Complete if Known	贡	20
Application Number	09/889,330	8	2
Filing Date	January 14, 2000	250	
First Named Inventor	Young	8	
Art Unit	1614		
Examiner Name	TBA		
Attorney Docket Number	030639.0027.UTL1		

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No.1	U.S. Patent Document Number Kind Code ² (if known)	Publication Date MMDDYYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
SWL	-AA	5,424,286	06-13-1995	Eng	

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FOREIGN PATENT DOCUMENTS						
Examiner Initials *	Cite No.1	Foreign Patent Document Country Code ³ Number ⁴ -Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵
SWL	AB	WO 97/46584	12-11-1997	Boehringer Mannheim GmgH	Cited in International Search Report (copy attached)	
Sivil	AC	WO 98/08871 -	03-05-1998	Novo Nordisk A/S		
らいし	AD	WO 98/30231	07-16-1998	Amylin Pharmaceuticals, Inc.		
ساسان	AE	WO 99/07404 •	02-18-1999	Amylin Pharmaceuticals, Inc.		
Sul	AF	WO 99/25727 - 🚜	05-27-1999	Amylin Pharmaceuticals, Inc.		
SivL	AG	WO 99/25728 ·	05-27-1999	Amylin Pharmaceuticals, Inc.		
Swl	AH	WO 99/40788 •	08-19-1999	Amylin Pharmaceuticals, Inc.		
SWL	ΑI	WO 99/43708 ⋅ ₺	09-02-1999	Novo Nordisk A/S		

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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<u> </u>	AJ	BHAVSAR et al., "Inhibition of Gastric Emptying and of Food Intake Appear to	
<i>اسک</i>	- •	be Independently Controlled in Rodents," 25 th Annual Meeting, November 11-16, 1995, San Diego, California, <u>Soc. Neurosci.</u> , 21:460 (Abstract) (188.8) (1995)	
	AK ,	D'ALESSIO et al., "Elimination of the Action of Glucagon-like Peptide 1 Causes an Impairment of Glucose Tolerance after Nutrient Ingestion by Healthy Baboons," J. Clin. Invest., 97(1):133-38 (1996)	
i	AL 0	DANIEL et al., "Use of Glucagon in the Treatment of Acute Diverticultis," <u>British Medical Journal</u> , 3:720-2 (1974)	
	AM	EISSELE et al., "Rat Gastric Somatostatin and Gastrin Release: Interactions of Exendin-4 and Truncated Glucagon-Like Peptide-1 (GLP-1) Amide," <u>Life Sci.</u> , 55(8):629-34 (1994)	3
	AN 6	ENG, "Prolonged Effect of Exendin-4 on Hyperglycemia of db/db Mice," <u>Diabetes</u> , 45(Supp 2):152A (abstract 554) (1996)	
	AO 4	ENG et al., "Purification and Structure of Exendin-3, a New Pancreatic Secretagogue Isolated from <i>Heloderma horridum</i> Venom," <u>J. Biol. Chem.</u> , 265(33):20259-62 (1990)	
	AP 9	ENG et al., "Isolation and Characterization of Exendin-4, an Exendin-3 Analogue, from <i>Heloderma suspectum</i> Venom," J. Biol. Chem., 267(11):7402-5 (1992)	
	AQ 1	GLAUSER et al., "Intravenous Glucagon in the Management of Esophageal Food Obstruction," J. Am. Coll. Emer. (JACEP), 8(6):228-231 (1979)	
	AR	GOKE et al., "Exendin-4 Is a High Potency Agonist and Truncated Exendin-(9-39)-amide an Antagonist at the Glucagon-like Peptide 1-(7-36)-amide Receptor of Insulin-secreting β-Cells," J. Biol. Chem., 268(26):19650-55 (1993)	
Swl	AS	KOLLIGS et al., "Reduction of the Incretin Effect in Rats by the Glucagon-Like Peptide 1 Receptor Antagonist Exendin(9-39) Amide," <u>Diabetes</u> , 44:16-19 (1995)	
Swe	AT •	MONTROSE-RAFIZADEH et al., "Structure-function Analysis of Exendin-4/	

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		GLP-1 Analogs," <u>Diabetes</u> , 45(Suppl. 2):152A (1996) [abstract 553]	
SwL	AU •	O'HALLORAN et al., "Glucagon-like Peptide-1 (7-36)-NH ₂ : a Physiological Inhibitor of Gastric Acid Secretion in Man," <u>J. Endocrinol.</u> , 126(1):169-73 (1990)	
	AV Ø	ØRSKOV et al., "Biological Effects and Metabolic Rates of Glucagonlike Peptide-1 7-36 Amide and Glucagonlike Peptide-1 7-37 in Healthy Subjects Are Indistinguishable," <u>Diabetes</u> , 42:658-61 (1993)	
	AW	RAUFMAN et al., "Exendin-3, a Novel Peptide from <i>Heloderma horridum</i> Venom, Interacts with Vasoactive Intestinal Peptide Receptors and a Newly Described Receptor on Dispersed Acini from Guinea Pig Pancreas," <u>J. Biol. Chem.</u> , 266(5):2897-902 (1991)	
	AX 1	RAUFMAN et al., "Truncated Glucagon-like Peptide-1 Interacts with Exendin Receptors in Dispersed Acini from Guinea Pig Pancreas", J. Biol. Chem. 267(30):21432-37 (1992)	
	AY	SCHEPP et al., "Exendin-4 and Exendin-(9-39)NH ₂ : Agonist and Antagonist, Respectively, at the Rat Parietal Cell Receptor for Glucagon-like Peptide-1-(7-36)NH ₂ ," <u>Eur. J. Pharm.</u> , 269:183-91 (1994)	
	AZ ∜	SCHJOLDAGER et al., "GLP-1 (Glucagon-like Peptide 1) and Truncated GLP-1, Fragments of Human Proglucagon, Inhibit Gastric Acid Secretion in Humans," <u>Digest. Dis. Sci.</u> , 34(5):703-8 (1989)	
	BA •	STOWER et al., "A Trial of Glucagon in the Treatment of Painful Biliary Tract Disease," Brit. J. Surg., 69:591-2 (1982)	. 1
	BB	THORENS et al., "Cloning and Functional Expression of the Human Islet GLP-1 Receptor," <u>Diabetes</u> , 42(11):1678-82 (1993)	
	BC ♥	THORENS, "Expression Cloning of the Pancreatic β Cell Receptor for the Gluco-incretin Hormone Glucagon-like Peptide 1," P. Natl. Acad. Sci. USA, 89:8641-45 (1992)	
	BD ,	TURTON et al., "A Role for Glucagon-like Peptide-1 in the Central Regulation of Feeding," Nature, 379(6560):69-72 (1996)	
SUL	BE 1	WANG et al., "Glucagon-like Peptide-1 Is a Physiological Incretin in Rat," <u>J.</u> Clin. Invest., 95:417-21 (1995)	

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SWL	BF	WETTERGREN et al., "Truncated GLP-1 (Proglucagon 78-107-Amide) Inhibits Gastric and Pancreatic Functions in Man," <u>Digest. Dis. Sci.</u> , 38(4):665-73 (1993)	
sw(BG	WILLMS et al., "Gastric Emptying, Glucose Responses, and Insulin Secretion after a Liquid Test Meal: Effects of Exogenous Glucagon-Like Peptide-1 (GLP-1)-(7-36) Amide in Type 2 (Noninsulin-Dependent) Diabetic Patients," J. Clin. Endocrinol. Metab., 81(1):327-32 (1996)	

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